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4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1044]

Shu Bei Yuan: Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) debarring Shu Bei Yuan for a period of 5 years from importing articles of food or offering such articles for importation into the United States. FDA bases this order on a finding that Ms. Yuan was convicted of one felony count under Federal law for conduct relating to the importation into the United States of an article of food. Ms. Yuan was given notice of the proposed debarment and an opportunity to request a hearing within the timeframe prescribed by regulation. As of December 31, 2012 (30 days after receipt of the notice), Ms. Yuan had not responded. Ms. Yuan's failure to respond constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit applications for termination of debarment to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Kenny Shade,

Office of Regulatory Affairs,

Food and Drug Administration,

12420 Parklawn Dr.,

Rockville, MD 20857,

301-796-4640.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(C) of the FD&C Act (21 U.S.C. 335a(b)(1)(C)) permits FDA to debar an individual from importing an article of food or offering such an article for import into the United States if FDA finds, as required by section 306(b)(3)(A) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any food.

On June 22, 2012, Ms. Yuan was convicted, as defined in section 306(l)(1)(B) of the FD&C Act, when the U.S. District Court for the Northern District of Illinois accepted her plea of guilty and entered judgment against her for the following offense: one count of entry of goods into the United States by means of false statements, in violation of 18 U.S.C. 542.

FDA's finding that debarment is appropriate is based on the felony conviction referenced herein for conduct relating to the importation into the United States of any food. The factual basis for this conviction is as follows: In or around March 2005 and continuing until in or around November 2005, Ms. Yuan conducted a scheme to fraudulently enter goods into the United States by means of false statements and documents in violation of 18 U.S.C. 542. The purpose of Ms. Yuan's scheme was to

import, enter, and sell Chinese-origin honey into the United States and avoid the payment of antidumping duties by falsely declaring to the U.S. Department of Homeland Security, Bureau of Customs and Border Protection (CBP) that the imported honey originated from countries other than China, including South Korea, when in fact Ms. Yuan knew that the honey originated from China.

Between August and November 2005, Ms. Yuan and others caused the fraudulent import and entry into the United States of approximately 26 entries of Chinese origin honey falsely declared as Korean honey, having a total declared entry value of approximately $808,287, thereby avoiding antidumping duties totaling approximately $1,485,631.

As a result of her conviction, on November 30, 2012, FDA sent Ms. Yuan a notice by certified mail proposing to debar her for a period of 5 years from importing articles of food or offering such articles for import into the United States. The proposal was based on a finding under section 306(b)(1)(C) of the FD&C Act that Ms. Yuan was convicted of a felony under Federal law for conduct relating to the importation into the United States of an article of food because she committed an offense related to the importation of Chinese honey into the United States by means of false statements.

The proposal was also based on a determination, after consideration of the factors set forth in section 306(c)(3) of the FD&C Act, that Ms. Yuan should be subject to a 5-year period of debarment. The proposal also offered Ms. Yuan an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Yuan

failed to respond within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Associate Commissioner for Regulatory Affairs, Office of Regulatory Affairs, under section 306(b)(1)(C) of the FD&C Act, and under authority delegated to the Associate Commissioner (Staff Manual Guide 1410.21), finds that Ms. Shu Bei Yuan has been convicted of a felony under Federal law for conduct relating to the importation of an article of food into the United States and that she is subject to a 5-year period of debarment.

As a result of the foregoing finding, Ms. Yuan is debarred for a period of 5 years from importing articles of food or offering such articles for import into the United States, effective (see DATES). Under section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of Ms. Yuan is a prohibited act.

Any application by Ms. Yuan for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2012-N-1044 and sent to the Division of Dockets Management (see ADDRESSES). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 28, 2013.

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Melinda K. Plaisier,
Acting Associate Commissioner for Regulatory Affairs,
Office of Regulatory Affairs.

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